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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,643	04/07/2006	Michelle Cayouette	564462004100	7609

7590  
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EXAMINER
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SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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05/19/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/530,643

Applicant(s)

CAYOQUETTE ET AL.

Examiner

SHERIDAN SWOPE

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009 and 13 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 1, 27, 33, 40, 45, 48, 57, 100, 106, 126, 131, 141, 173, 174, 205, 206, and 214 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 60, 98, 175, 180, 185, 190, 196, 198, 202, 204, 212, 213, 218-221, 226-229 is/are rejected.
- 7) ☒ Claim(s) 223-225 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-652)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-419)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are

1,27,33,40,45,48,57,60,98,100,106,126,131,141,173-175,180,185,190,196,198,202,204-206,212-214,218-221 and 223-229.

### **DETAILED ACTION**

Applicants' filings of February 18 and April 13, 2009, in response to the action mailed September 18, 2008, are acknowledged. It is acknowledged that Claims 60, 98, 175, 180, 185, 190, 196, 198, 202, 204, 212, 213, and 218-221 have been amended and Claims 223-229 have been added. Claims 1, 27, 33, 40, 45, 48, 57, 60, 98, 100, 106, 126, 131, 141, 173-175, 180, 185, 190, 196, 198, 202, 204-206, 212-214, 218-221, and 223-229 are pending. Claims 1, 27, 33, 40, 45, 48, 57, 100, 106, 126, 131, 141, 173, 174, 205, 206, and 214 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 60, 98, 175, 180, 185, 190, 196, 198, 202, 204, 212, 213, 218-221, and 223-229 are hereby considered.

#### ***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### **Enablement**

Rejection of Claims 60, 98, 175, 180, 185, 190, 196, 198, 202, 204, 212, 213, and 218-221 under 35 U.S.C. 112, first paragraph/enablement, for essentially the same reasons explained in the prior action, is maintained. New Claims 226-229 are herein rejected under 35 U.S.C. 112, first paragraph/enablement, for the same reasons. In support of their request that said rejection be withdrawn, Applicants argue that the claims have been narrowed in scope to encompass polypeptides having at least 90% identity over the full length of SEQ ID NO:42 and also having protease activity.

This argument is not found to be persuasive for the following reasons. The specification fails to provide sufficient guidance such that the making and using of all polypeptides having at least 90% with SEQ ID NO: 42, and having protease activity, does not represent undue experimentation. In addition, as explained in the prior action, the specification does not establish: “(B) which encompassed polypeptides have the functions recited in Claims 60, 180, 185, 190, 196, 198, 202, 204, 212, 213, and 218-221; (C) regions of the protein structure which may be modified without affecting the desired activity; (D) the general tolerance of the desired activity to modification and extent of such tolerance; (E) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (F) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful”. Claims 226-229 are rejected under 35 U.S.C. 112, first paragraph/enablement, for the same reasons.

For these reasons and those explained in the prior action, Claims 60, 98, 175, 180, 185, 190, 196, 198, 202, 204, 212, 213, 218-221, and 226-229 are rejected under 35 U.S.C. 112, first paragraph/enablement.

### **Written Description**

Rejection of Claims 175, 180, 185, 190, 196, 198, 202, 204, 212, 213, and 218-221 under 35 U.S.C. 112, first paragraph/written description, for essentially the same reasons explained in the prior action, is maintained. New Claims 226, 227, and 229 are herein rejected under 35 U.S.C. 112, first paragraph/enablement, for the same reasons. In support of their request that said rejection be withdrawn, Applicants argue that the claims have been narrowed in scope to

encompass polypeptides having at least 90% identity over the full length of SEQ ID NO:42 and also having protease activity.

This argument is not found to be persuasive for the following reasons. As explained in the prior action, the specification does not describe the genera of polypeptides, having the structures and functions recited in Claims 175, 180, 185, 190, 196, 198, 202, 204, 212, 213, and 218-221, in a manner such that the skilled artisan would recognize Applicants were in possession of said genera. Claims 226, 227, and 229 are rejected under 35 U.S.C. 112, first paragraph/enablement, for the same reasons.

For these reasons and those explained in the prior action, Claims 175, 180, 185, 190, 196, 198, 202, 204, 212, 213, 218-221, 226, 227, and 229 are rejected under 35 U.S.C. 112, first paragraph/written description.

***Allowable Subject Matter***

No claims are allowable. Claims 223-225 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

#### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-092834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652